

AMENDED IN ASSEMBLY JUNE 2, 2003
AMENDED IN ASSEMBLY APRIL 29, 2003
AMENDED IN ASSEMBLY APRIL 22, 2003
AMENDED IN ASSEMBLY MARCH 25, 2003
AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 103

Introduced by Assembly Members Reyes and Koretz
(Coauthors: Assembly Members Hancock and Lieber)
(Coauthors: Senators Chesbro, Romero, and Soto)

January 10, 2003

An act to add Chapter 8 (commencing with Section 119400) to Part 15 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

Under existing law, the State Department of Health Services generally regulates the safety, content, packaging, advertising, and use of various food and drug products.

This bill would require a pharmaceutical manufacturing company, as defined, on or before January 1 of each year, to disclose to the Bureau of Food and Drug of the department the name of the recipient, and the value, nature, and purpose of any gift, fee, payment, subsidy, or other

economic benefit the company provided directly, or through its pharmaceutical marketers or wholesale distributors, to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or other specified person, except as provided. This bill would also require the department to report to the Governor and the Legislature on or before March 1 of each year, commencing in 2005, the information so disclosed.

The bill would also require a pharmaceutical manufacturing company to disclose to the department, on or before October 1, 2004, and annually thereafter, the name and address of the individual responsible for the company's compliance with the provisions of the bill.

~~This bill would prohibit any person or entity from engaging in the inappropriate marketing, as defined, of any dangerous drug or device to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California who is authorized to prescribe, dispense, or purchase dangerous drugs in this state.~~

~~Existing provisions of the Political Reform Act of 1974 prohibit specified state officials and candidates for state office from accepting gifts in excess of a specified amount.~~

~~This bill would prohibit a pharmaceutical manufacturing company, as defined, from annually giving any gift, fee, payment, subsidy, or other economic benefit, except as specified, to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state that is more than the gift limit amount specified in existing regulations concerning gifts to state officials.~~

~~The bill would impose authorize the imposition of a civil penalty in the amount of \$10,000, enforceable by the department, the Attorney General, or a private party, for the violation of its these requirements.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Chapter 8 (commencing with Section 119400)
- 2 is added to Part 15 of Division 104 of the Health and Safety Code,
- 3 to read:
- 4

CHAPTER 8. DRUG MARKETING PRACTICES

~~119400. (a) No person or entity may engage in inappropriate~~
119400. (a) On or before January 1 of each year, a pharmaceutical manufacturing company shall disclose to the Bureau of Food and Drug of the department the name of the recipient, and the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit the company provided directly, or through its pharmaceutical marketers or wholesale distributors, in connection with detailing, promotional, or other marketing activities, to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state.

(b) Disclosure shall be made on a form and in a manner prescribed by the department. The initial disclosure shall be made on or before January 1, 2005, for the period beginning on July 1, 2003, and ending June 30, 2004. The department shall report to the Governor and the Legislature on or before March 1 of each year, commencing in 2005, the information disclosed to it pursuant to this section.

(c) The department shall not disclose information identified as a trade secret by the pharmaceutical manufacturing company in its disclosure statements.

(d) A pharmaceutical manufacturing company shall also disclose to the department, on or before October 1, 2004, and annually thereafter, the name and address of the individual responsible for the company's compliance with this section.

(e) The following are exempt from disclosure under this section:

(1) A complimentary sample of a dangerous drug intended to be furnished to a patient.

(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial.

(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars (\$25).

(f) A civil penalty in the amount of ten thousand dollars (\$10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty may be assessed. The prevailing plaintiff

1 *in the action shall be awarded costs and reasonable attorney's fees*
2 *in addition to the civil penalty. If the department is the prevailing*
3 *plaintiff, the civil penalty, costs, and attorney's fees shall be*
4 *deposited into the General Fund.*

5 (g) *The following definitions apply for purposes of this section:*

6 (1) *"Clinical trial" means an approved clinical trial conducted*
7 *in connection with a research study designed to answer specific*
8 *questions about vaccines, new therapies, or new ways of using*
9 *known treatments.*

10 (2) *"Pharmaceutical manufacturing company" means an*
11 *entity that is engaged in the production, preparation, propagation,*
12 *compounding, conversion, or processing of dangerous drugs,*
13 *either directly or indirectly, by extraction from substances of*
14 *natural origin or independently by means of chemical synthesis or*
15 *by a combination of extraction and chemical synthesis.*
16 *"Pharmaceutical manufacturing company" also means an entity*
17 *engaged in the packaging, repackaging, labeling, relabeling, or*
18 *distribution of dangerous drugs. 'Pharmaceutical manufacturing*
19 *company' does not include a drug wholesaler or a licensed*
20 *pharmacist.*

21 (3) *"Pharmaceutical marketer" means a person who, while*
22 *employed by or under contract to represent a pharmaceutical*
23 *manufacturing company, engages in pharmaceutical detailing,*
24 *promotional activities, or other marketing of a dangerous drug in*
25 *this state to a physician, hospital, nursing home, pharmacist,*
26 *health benefit plan administrator, or any other person authorized*
27 *to prescribe, dispense, or purchase a dangerous drug.*
28 *"Pharmaceutical marketer" does not include a representative of*
29 *a drug wholesaler who otherwise markets the services of a drug*
30 *wholesaler in connection with a dangerous drug.*

31 (4) *"Dangerous drug" means any drug that is unsafe for self-use*
32 *and includes any of the following:*

33 (A) *Any drug that bears the legend "Caution: federal law*
34 *prohibits dispensing without prescription," "Rx only," or words of*
35 *similar import.*

36 (B) *Any drug or device that, pursuant to federal or state law,*
37 *may be dispensed only on prescription, or that is furnished*
38 *pursuant to Section 4006 of the Business and Professions Code.*

39 *"Dangerous drug" does not include labeled veterinary drugs.*

1 ~~marketing of any dangerous drug or device to a physician, hospital,~~
2 ~~nursing home, pharmacist, health benefit plan administrator, or~~
3 ~~any other person in California authorized to prescribe, dispense,~~
4 ~~or purchase dangerous drugs in this state.~~

5 ~~(b) For purposes of this section, “inappropriate marketing”~~
6 ~~means any action intended to entice a physician or other medical~~
7 ~~provider to employ a dangerous drug or device in the treatment of~~
8 ~~a patient by offering any of the following:~~

9 ~~(1) Cash payments to physicians of any kind.~~

10 ~~(2) Gifts to physicians that are not directly related to the benefit~~
11 ~~of the patient or the practice of the physician related to the~~
12 ~~dangerous drug or device.~~

13 ~~(3) Any cost for litigation in relation to the prescription of a~~
14 ~~dangerous drug or device.~~

15 ~~(4) Travel, meals, or lodging for the physician unless they are~~
16 ~~associated with legitimate physician education.~~

17 ~~119401. (a) A pharmaceutical manufacturing company shall~~
18 ~~not provide to a physician, hospital, nursing home, pharmacist,~~
19 ~~health benefit plan administrator, or any other person in California~~
20 ~~authorized to prescribe, dispense, or purchase dangerous drugs in~~
21 ~~this state any gift, fee, payment, subsidy, or other economic benefit~~
22 ~~in any calendar year in excess of the gift limit amount as described~~
23 ~~in Section 18940.2 of Title 2 of the California Code of~~
24 ~~Regulations, either directly or through its pharmaceutical~~
25 ~~marketers or wholesale distributors, in connection with detailing,~~
26 ~~promotional, or other marketing activities.~~

27 ~~(b) A physician, hospital, nursing home, pharmacist, health~~
28 ~~benefit plan administrator, or any other person in California~~
29 ~~authorized to prescribe, dispense, or purchase dangerous drugs in~~
30 ~~this state shall not accept gifts, fees, payments, subsidies, or other~~
31 ~~economic benefits in any calendar year with a total value greater~~
32 ~~than the gift limit amount as described in Section 18940.2 of Title~~
33 ~~2 of the California Code of Regulations, provided either directly~~
34 ~~by a pharmaceutical manufacturing company or through its~~
35 ~~pharmaceutical marketers or wholesale distributors, in connection~~
36 ~~with detailing, promotional, or other marketing activities.~~

37 ~~(c) The following shall not be assessed as a gift as described in~~
38 ~~subdivisions (a) and (b):~~

39 ~~(1) A complimentary sample of a dangerous drug intended to~~
40 ~~be furnished to a patient.~~

~~(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial of a dangerous drug.~~

~~(3) Any economic benefit received through contracting for the gross purchase of dangerous drugs or medical devices.~~

~~(d) The following definitions apply for purposes of this chapter:~~

~~(1) "Clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.~~

~~(2) "Dangerous drug" means any drug that is unsafe for self-use and includes any of the following:~~

~~(A) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.~~

~~(B) (i) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.~~

~~(ii) "Dangerous drug" does not include labeled veterinary drugs.~~

~~(3) (A) "Pharmaceutical manufacturing company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.~~

~~(B) "Pharmaceutical manufacturing company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.~~

~~(4) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional, or other marketing activities of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug.~~

~~119402. (a) Any pharmaceutical manufacturing company, physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to~~

1 ~~prescribe, dispense, or purchase dangerous drugs in this state who~~
2 ~~willfully and knowingly violates any provision of this chapter~~
3 ~~shall be liable for a civil penalty of not more than ten thousand~~
4 ~~dollars (\$10,000) for each violation. Each violation of these~~
5 ~~sections constitutes a separate offense for which the civil penalty~~
6 ~~may be assessed. The prevailing plaintiff in the action shall be~~
7 ~~awarded costs and reasonable attorney's fees in addition to the civil~~
8 ~~penalty. The State Department of Health Services, the Attorney~~
9 ~~General, or a private party may bring a civil action to enforce the~~
10 ~~provisions of this chapter.~~

11 ~~(b) Nothing in this chapter shall be construed to impair or~~
12 ~~impede a licensing agency's authority under any other provision~~
13 ~~of law.~~

